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Mr. Barnes Johnson
Director
Office of Resource Conservation and Recovery
U.S. EPA
Two Potomac Yard (North Building)
2733 Crystal Drive
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Certified Mail Return Receipt Requested

Re: **RCRA Regulatory Interpretation for E-Cigarettes**

Dear Mr. Johnson:

I am writing on behalf of a client that is considering the manufacture and sale of e-cigarettes to retailers. The purpose of this letter is to seek EPA's determination regarding the hazardous waste status of e-cigarettes under RCRA.[1] It appears to me that e-cigarettes are best categorized as "manufactured articles," and, therefore, should not be regulated as hazardous waste commercial chemical products ("CCPs"). However, this conclusion is less than certain, and so I am seeking EPA's interpretation.

E-Cigarettes

An e-cigarette is a fairly complex electronic device meant to simulate smoking a traditional cigarette. With some variation, most e-cigarettes consist of the following components:

- A steel tube housing, approximately the size of a traditional cigarette.
- An air flow sensor and LED light (to mimic burning ash).
- Plastic or rubber caps, bases, holders, stoppers, nozzles and other structural pieces.
- A lithium ion battery. The battery may be non-chargeable or may be rechargeable using a wall, USB, or car charger.
- A heater/atomizer, generally consisting of a wick and heating coil.

[1] The Food and Drug Administration intends to issue new regulations to regulate product labeling, sale and similar requirements for e-cigarettes in the near future, but those regulations are unlikely to touch on waste issues.

- Cotton/poly absorbent filler that is used to absorb and hold "e-liquid." This material is sometimes a component of the cigarette, or is contained in either a pre-filled or re-fillable cartridge that is inserted into the cigarette.
- A small amount (approximately 1 mL) of e-liquid. E-liquid consists of a mixture of 1 – 2.5% nicotine, some flavorings,[2] and then propylene glycol, vegetable glycerin, polyethylene glycol 400, or a mix of these liquids.[3]

When an individual inhales, the battery powers the internal heating element, which causes the e-liquid to vaporize, delivering the flavored vapor and nicotine to the user. My client intends to make and sell only pre-filled e-cigarettes. Therefore, the nicotine solution will be incorporated into the e-cigarette and will not come in a separate cartridge or container.

Commercial Chemical Products

CCPs are a category of listed hazardous waste under RCRA. Generally, a material[4] is regulated as a CCP when it is discarded, applied to land, or used to produce fuels. 40 C.F.R. § 261.33. The RCRA regulations define CCPs by "generic name," which are listed in tables in the regulations. The comments included in the regulations explain that the term "commercial chemical product" includes (1) "commercially pure" or "technical" grades of the chemical and (2) "all formulations in which the chemical is the sole active ingredient." 40 C.F.R. § 261.33(d). "Nicotine and salts" are listed as the acute CCP waste P075.

In 1980, EPA explained the intent behind listing CCPs:

> EPA intended to encompass those chemical products which possessed toxic or other hazardous properties and which, for various reasons, are sometimes thrown away in pure or undiluted form. The reasons for discarding these materials might be that the materials did not meet required specifications, that inventories were being reduced, or that the product line had changed. The regulation was intended to designate chemicals themselves as hazardous wastes, if discarded, not to list all wastes which might contain these chemical constituents.

[2] Traditional tobacco flavor, menthol, etc.

[3] These are FDA-approved non-toxic liquids, with a slightly sweet taste, which are used in pharmaceuticals and as food additives and preservatives. Vegetable glycerin is a sugar-alcohol compound. Propylene glycol is used as a food preservative and is also commonly used in pharmaceuticals. It is also the solution used to create theatrical smoke. Polyethylene glycol 400 is a similar solution that is used in a variety of pharmaceutical formulations. None of these materials qualify as listed or characteristic hazardous wastes.

[4] These materials include a manufacturing chemical intermediate, off-spec chemical, and container/spill residue. 40 C.F.R. § 261.33(b) and (c).

U.S. EPA, *Final Rule, Final Interim Rule: Hazardous Waste Management System Identification and Listing of Hazardous Waste,* 45 Fed. Reg. 33084, 33115 (May 19, 1980). Overall, it appears that the intent was to regulate the disposal of unused and relatively "pure or undiluted" chemicals.

Manufactured Articles

EPA has since used the concept of "manufactured articles" to help explain and delineate the types of materials that are regulated as CCPs. The general rule is that a manufactured article that contains a listed chemical is not regulated as a CCP. For example, when EPA first promulgated the CCP list in 1980, EPA noted that batteries and mercury vapor lights were "manufactured articles," not CCPs, reasoning that:

> EPA intends that the materials listed in §261.33 include only those commercial chemical products . . . that are known by the generic name of the chemicals listed . . . . Manufactured articles that contain any of the chemicals listed . . . are rarely, if ever, known by the generic name of the chemical(s) they contain and, therefore, are not covered . . . .

EPA, *Final Rule: Hazardous Waste Management System, Identification and Listing of Hazardous Waste,* 45 Fed. Reg. 78532, 78541 (Nov. 25, 1980). Since 1980, EPA has determined that mercury thermometers, batteries, mercury vapor lights, chemically-treated blankets and other similar products are "manufactured articles," and, therefore, are not subject to regulation as CCPs, even though they contain CCP-listed chemicals. In so doing, EPA reiterated that the CCP regulations apply to materials "known by the generic chemical name" listed in the CCP tables, and, accordingly, thermometers and fluorescent lamps were not CCPs because (among, apparently, other reasons) they are not known by the listed generic chemical name "mercury." RCRA Online Number 14012 (August 1, 1996). See also RCRA Faxback 13310 (August 1989) (discussing thermometers).[5]

Given the above reasoning, it appears that "e-cigarettes" fall into the category of "manufactured articles" and are not CCPs. First, e-cigarettes are not known by the generic chemical name "nicotine," evidencing that they are not the type of "pure" substance or solution that EPA intended to regulate. Second, an e-cigarette is very similar to the devices that EPA has deemed to be "manufactured articles" in the past. For example, an e-cigarette is comparable to both a thermometer (a tube containing a small amount of chemical) and a lamp (an electronic

[5] While not definitive, the "generic name" concept has turned into a sort of short-hand means to help identify CCPs in manufacturing settings, especially when making waste determinations for mixtures and formulations, and I use it to help explain the concept to my clients. *See also McCoy's RCRA Unraveled,* p. 118 (2010 Ed.) ("In most cases, if the main entry on the label on whatever you are discarding is the name of a chemical on the P- or U-list, it will be pure enough to be regulated.")

device containing a small amount of chemical). In 1992, EPA took another look at this issue in relation to chemically-treated blankets, and concluded that the blankets were not regulated as CCPs: "The hazardous wastes identified in §261.33 are the discarded chemical substances themselves, not discarded products which have been treated with the chemical." RCRA Online Number 11711 (November 17, 1992). E-cigarettes are also similar to chemically-treated blankets, in that an e-cigarette contains a cotton/poly absorbent material with a dilute nicotine solution added to it.

On the other hand, EPA has concluded that some nicotine-containing pharmaceuticals *are* regulated as CCPs, including nicotine gum, caplets, lozenges and transdermal patches. In the case of nicotine patches, in 1995, EPA reversed a prior determination that nicotine patches were "manufactured articles," and, instead, held that the patches were regulated as P075 CCP waste:

> . . . we do not view dermal patches to be 'manufactured articles.' Nicotine patches are used to deliver the listed chemical in a certain dosage and may be generically referred to as the active chemical ingredient. Therefore, the use of these patches flows directly from the listed chemical.

RCRA Online Number 13741 (April 1995). Unlike a "nicotine patch," however, e-cigarettes are never known as "nicotine cigarettes," but instead are known as "e" or "electronic-cigarettes." This reflects the fact that while the sole purpose of a nicotine patch is to deliver nicotine to the user, an e-cigarette is more complex (and is more expensive because of it). For example, an e-cigarette is also designed to deliver a flavored "smoke" to the user by vaporizing flavorings and glycol, to "light up," and to otherwise mimic the look and feel of a real cigarette.

Finally, compared to a patch (or a lozenge, caplet, or stick of gum), an e-cigarette is a complicated mechanism that, fundamentally, simply looks less like a "formulation" and more like a "manufactured article." It contains a battery (which, in itself, could be a universal waste) and an electronically driven heater/atomizer. Further, an e-cigarette contains very little actual nicotine. According to my client, their e-cigarette would contain approximately 65 mgs of nicotine when full, which translates into approximately 0.5% of the total weight of the product. Most of the e-cigarette is metal, plastic and battery.

My client does not foresee having to manage or dispose of large quantities of e-cigarettes. However, it is possible that damaged or expired e-cigarettes could be returned to them (or to their reverse distributor), in which case, a waste determination would have to be made. Small quantities of waste e-cigarettes could also be generated during the manufacturing process.

I appreciate any guidance that you can give me on this matter. Thank you for your time.

Very truly yours

Daniel K. DeWitt

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